Complete Summary

GUIDELINE TITLE

Myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction. London (UK): National Institute for Clinical Excellence (NICE); 2003 Nov. 25 p. (Technology appraisal; no. 73).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Coronary artery disease (angina and myocardial infarction)

GUIDELINE CATEGORY

Diagnosis
Evaluation
Technology Assessment

CLINICAL SPECIALTY

Cardiology
Internal Medicine
Nuclear Medicine
Radiology

INTENDED USERS

Advanced Practice Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To assess the clinical and cost-effectiveness of myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction

TARGET POPULATION

Adults with diagnosed or suspected coronary artery disease (angina and myocardial infarction)

INTERVENTIONS AND PRACTICES CONSIDERED

Myocardial perfusion scintigraphy (MPS) using single photon emission computed tomography (SPECT)

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
    - For studies of diagnostic accuracy, the types of outcomes included were either the absolute numbers of true positives, false positives, false negatives, and true negatives, or the sensitivity and specificity values.
    - For studies of prognosis, risk assessment, stratification and patient management, the types of outcomes included were: mortality; cardiac mortality; nonfatal MI; revascularisation (percutaneous transluminal coronary angioplasty [PTCA]/ coronary artery bypass graft [CABG]); occurrence of unstable angina; length of survival free of cardiac death; preservation of left ventricular function (after surgery); post-operative complications; number of CAs performed; hospital admissions; and quality of life measures.
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the Health Services Research Unit (HSRU), University of Aberdeen (see the "Companion Documents" field).

Search Strategy

Initial searches were undertaken to identify relevant systematic reviews, Health Technology Assessment (HTA) reports and other evidence-based reports. A list of databases and web pages searched are given in Appendix 1 of the assessment report.

Electronic searches were conducted to identify published and unpublished studies on the clinical and cost-effectiveness of single photon emission computed tomography (SPECT) myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction. The following databases were searched and full details of the searches are documented in Appendix 1 of the assessment report:

1. MEDLINE 1966 - Oct 2002, EMBASE 1980-2002 (to week 44)

   Separate search strategies were developed for each database and then combined to produce a final strategy that was run concurrently on the four databases. Duplicates were removed from the resulting set using Ovid's de-duplicating feature.

2. PREMEDLINE (Ovid) 5th November 2002
3. BIOSIS (Edina) 1985 - December 2002
4. Science Citation Index (Web of Science) 1981 - December 2002
5. The Cochrane Library (Issue 3 2002). (CENTRAL)
6. Health Management Information Consortium (HCN) 1979 - 2002
7. HTA Database (National Health Service [NHS] Centre for Reviews & Dissemination) October 2002

References of included studies were also checked.

All titles and abstracts identified were assessed to identify potentially relevant items. For all these items, full text papers were obtained and assessed independently for inclusion by two researchers, using a study eligibility form developed for this purpose. Any disagreements that could not be resolved through discussion were referred to an arbiter.

Inclusion and Exclusion Criteria

Types of Study

Prospective and retrospective primary studies of SPECT myocardial perfusion scintigraphy (MPS) compared with any of the interventions noted under Types of Interventions below for the diagnosis, prognosis, risk assessment, stratification and management of patients with suspected or confirmed coronary heart disease were included.

The following kinds of reports were not considered: abstracts; case reports; pictorial essays; pilot, volunteer, phantom, animal or safety studies; studies investigating technical aspects of SPECT MPS or the development of imaging acquisition or processing. Studies reported in non-English languages were noted (details available from the authors) but not included in the review.

Studies with less than 100 participants were excluded.

Types of Participants

Adults with suspected or diagnosed coronary heart disease were included, with the exception of pregnant women. Subgroup analysis was planned on:

a. Patients who have experienced previous myocardial infarction (MI); and
b. Women

The following types of patients were excluded: patients who had received heart transplants; patients with hypertrophic cardiomyopathy, mitral valve prolapse, primary aldosteronism, lupus, acromegaly, cystic fibrosis, severe obstructive sleep apnoea, betathalassemia, and patients who had undergone aortic reconstruction.

The role of MPS in patients unable to exercise or with abnormal resting electrocardiogram (ECG) was not specifically considered.

Types of Interventions

The interventions included were:

- SPECT (including ECG-gated SPECT and attenuation-corrected SPECT) as part of the clinical care pathways. Planar imaging was excluded. The types of radionuclides considered relevant were thallium-201, technetium-99m sestamibi or technetium 99-m tetrofosmin. The types of stress included were exercise (treadmill or bicycle) or pharmacological (adenosine or dipyridamole or dobutamine) or a combination of exercise and pharmacological means.
- Stress ECG
- Coronary angiography (CA)

For studies of diagnostic accuracy the interventions included were SPECT versus stress ECG, with CA as the reference standard test. In situations where CA would be an inappropriate reference standard (e.g. patients with mild clinical symptoms), clinical follow-up was accepted as the reference standard.

For prognostic studies, strategies involving SPECT were compared with strategies that did not. These included:

- Stress ECG/SPECT/CA versus stress ECG/CA
- Stress ECG/SPECT versus stress ECG alone
- SPECT/CA versus CA alone
- Stress ECG versus SPECT versus CA
- SPECT versus CA
- Stress ECG versus SPECT

Studies were also included that compared SPECT with ECG-gated SPECT or attenuation-corrected SPECT (in any combination).

Types of Outcomes

See "Major Outcomes Considered."

NUMBER OF SOURCE DOCUMENTS

In total, 70 studies, published in 71 reports, met the inclusion criteria for studies of effectiveness. There were 21 diagnostic studies, 46 prognostic studies, two studies assessing electrocardiogram (ECG)-gated single photon emission computed tomography (SPECT) and one study assessing attenuation-corrected SPECT.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data Extraction Strategy

A data extraction form was used (see Appendix 2 of assessment report) to record details of study design, methods, participants, interventions, testing procedures, outcomes and follow-up. Two reviewers extracted data independently. Differences that could not be resolved through discussion were referred to an arbiter. Reviewers were not blinded to the names of study authors, institutions or publications.

Quality Assessment Strategy

The methodological quality of the diagnostic studies was assessed using the quality assessment of diagnostic accuracy studies (QUADAS) tool developed by the National Health Service (NHS) Centre for Reviews and Dissemination (see Appendix 3 of assessment report). The tool did not incorporate a quality score but was a structured list of 12 questions, covering areas such as spectrum and verification bias, with each question to be answered 'Yes', 'No' or 'Unclear'. Two reviewers independently assessed the quality of the included studies. Any differences that could not be resolved through discussion were referred to an arbiter.

The prognostic studies were assessed using the Downs and Black checklist (see Appendix 4 of assessment report). The checklist assessed the quality of both randomised and non-randomised studies (including cohort studies). Question 27 (study power) was omitted as studies with less than 100 participants were excluded. The adapted checklist, therefore, contained 26 questions, covering the following subscales:

- Reporting (ten questions)
- External validity (three questions)
- Internal validity - bias (seven questions)
- Internal validity - confounding (six questions)

An overall score as well as scores for each of the subscales was calculated. A list of principal confounders and possible adverse events was developed (see Appendix 5 of assessment report) to provide supplementary information to questions 5 and 8 of the checklist. The maximum achievable scores within each subscale were: reporting (11), external validity (3), internal validity - bias (7) and internal validity - confounding (6) providing an overall maximum achievable score of 27.

Synthesis of Diagnostic Studies

Diagnostic performance indexes (sensitivity, specificity, accuracy, predictive values, and likelihood ratios) were extracted and recalculated for each study for both tests (single photon emission computed tomography (SPECT) versus coronary angiography (CA) and stress electrocardiogram (ECG) versus CA) and 2x2 contingency tables of true positive, false positive, false negative and true negative were generated. For studies with missing data (e.g. studies reporting only sensitivity and specificity values) an attempt was made to reconstruct the contingency tables from the data available in the published reports. This proved to be feasible only when the total number of participants, sensitivity, specificity, and accuracy were provided or when the total number of participants, sensitivity, specificity, positive and negative likelihood ratios were known.

Details of the mathematical formulae applied are given in Appendix 6 of the assessment report. Use of the formulae was not always straightforward because in many cases they yielded noninteger values of true positives, false positives, false negatives and true negatives. This was usually because published values of sensitivity and specificity were often given to just two decimal places. In most cases it was possible to find integer values for the contingency tables that yielded

the corresponding published values of sensitivity and specificity using the formulae described above. There was, however, a minority of comparisons where no exact match could be found. For example, for the Santana-Boado study the chosen integer values for the 2x2 table for the SPECT versus CA comparison yielded a sensitivity of 0.917 but the reported value of sensitivity was 0.91 and not 0.92. In these cases it was decided to use the data providing the closest match to the published values as the differences were not great and it is likely that the discrepancies were caused by rounding errors.

For the statistical analysis of studies of diagnostic performance the methods suggested by Midgette and colleagues were applied (see Figure 3.1 of the assessment report). They first advocate plotting the true positive rate (sensitivity) versus the false positive rate (1 - specificity) and calculating the Spearman's rank correlation coefficient. If a large positive correlation is noted then this is an indication that calculation of a summary receiver operating characteristic (ROC) curve is desirable. In the absence of a positive correlation, heterogeneity between true and false positive rates is tested using a chi-squared test (or an extension of Fisher's exact test if the numbers are too small). If the data are homogenous it is reasonable to conduct meta-analyses of sensitivities and specificities. Conversely, when data are heterogeneous and not positively correlated a statistical summary is not recommended.

Summary ROC curves for SPECT versus CA and stress ECG versus CA were considered when a positive correlation between the true and false positive rates was found and when a sufficient number of studies was available for each comparison. A ROC curve for a test with high discriminatory power should yield a "path" close to the top-left corner of the plot, indicating that it provides a high true positive rate and a low false positive rate. It is commonly used to describe how different test cut-off points affect the trade-off between sensitivity and specificity.

If appropriate, it was planned to calculate pooled estimates of sensitivity and specificity and their confidence intervals for both SPECT and stress ECG for each comparison. These are averages of the sensitivities and specificities weighted by the inverse of the variance of each study. Studies for which 2x2 table information could not be obtained could not be included in this analysis.

In addition, meta-analyses of positive and negative likelihood ratios were conducted where appropriate. Likelihood ratios express the probability that a certain test result is expected in a patient with the target disorder, as opposed to one without the disorder. For instance, a likelihood ratio of 10 means that a positive test result is 10 times as likely to occur in patients having the disease under investigation (i.e. coronary artery disease [CAD]) than in healthy subjects. A likelihood ratio of one means that the test result does not provide diagnostic information and does not change the probability of the target condition. Likelihood ratios below one indicate a decrease in the probability of the target condition (the smaller the likelihood ratio, the greater the decrease). As likelihood ratios are identical in construction to risk ratios, meta-analyses of positive and negative likelihood ratios were conducted using a random effects model and treated as meta-analyses of risk ratios.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients, and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who

are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The Assessment Group, the manufacturer and the professional group reviewed published cost-effectiveness studies. The Assessment Group and the manufacturer also provided new economic models.

In summary, when compared with stress electrocardiography-coronary angiograph (sECG-CA), single photon emission computed tomography-coronary angiography (SPECT-CA) has more favourable incremental cost-effectiveness ratios (ICERs) than direct CA at low levels of prevalence of coronary artery disease. At higher prevalence levels, the sECG-CA and CA strategies lead to more favourable ICERs than SPECT-CA.

See Section 4.2 of the original guideline document for a detailed discussion of the cost-effectiveness analysis.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

This appraisal covers the use of myocardial perfusion scintigraphy (MPS) using single photon emission computed tomography (SPECT) in the diagnosis and

management of angina and myocardial infarction. It does not cover planar MPS or the use of MPS in the management of heart failure or in the assessment of myocardial viability. In this guidance the term coronary artery disease (CAD) is used to refer to angina and myocardial infarction.

- MPS using SPECT is recommended for the diagnosis of suspected coronary artery disease (CAD) in the following circumstances.
    - As the initial diagnostic tool for people with suspected CAD for whom stress electrocardiography poses particular problems of poor sensitivity or difficulties in interpretation, including women, patients with cardiac conduction defects (for example, left bundle branch block), and people with diabetes, and for people for whom treadmill exercise is difficult or impossible.
    - As part of an investigational strategy for the diagnosis of suspected CAD in people with lower likelihood of CAD and of future cardiac events. The likelihood of CAD will be based on the assessment of a number of risk factors including age, gender, ethnic group, family history, associated comorbidities, clinical presentation, physical examination, and results from other investigations (for example, blood cholesterol levels or resting electrocardiogram).
- MPS using SPECT is recommended as part of the investigational strategy in the management of established CAD in people who remain symptomatic following myocardial infarction or reperfusion interventions.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

For clinical effectiveness, much of the evidence consisted of nonrandomised open observational (both prospective and retrospective) studies, with several studies using a comparative design.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of myocardial perfusion scintigraphy in patients with angina and myocardial infarction to obtain information for diagnosis and evaluation while minimizing expenditure

POTENTIAL HARMS

The complication rates for single photon emission computed tomography (SPECT) are usually related to exercise or pharmacological stimulation given as part of the

stress component in the procedure, with an associated mortality of around 0.01% and a morbidity of around 0.02%.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- These recommendations contain advice that may result in some medicines being prescribed outside the terms of their marketing authorisation. Clinicians prescribing these drugs should ensure that patients are aware of this, and that they consent to their use in such circumstances.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation and Audit

- National Health Service (NHS) hospitals and all clinicians who care for people with coronary artery disease (CAD) should review current diagnostic options available to take account of the guidance.
- Local guidelines or care pathways for people with CAD should incorporate the guidance.
- To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in Appendix C of the original guideline document.
- Myocardial perfusion scintigraphy (MPS) using single photon emission computed tomography (SPECT) is carried out for the diagnosis of individuals with suspected CAD in the following circumstances.
    - As the initial diagnostic tool for an individual with suspected CAD for whom stress electrocardiogram (sECG) poses problems of poor sensitivity or difficulties in interpretation, and for an individual for whom treadmill exercise is difficult or impossible.
    - As part of an investigational strategy for the diagnosis of suspected CAD in an individual who has a lower likelihood of CAD and of future cardiac events.
- MPS using SPECT is carried out as part of an investigational strategy in the management of established CAD in an individual who remains symptomatic following myocardial infarction or reperfusion interventions (coronary artery bypass graft [CABG] or percutaneous coronary intervention [PCI]).
- Local clinical audits on the care of patients with CAD could also include criteria for the management of CAD based on the national standards, including standards in the National Service Framework.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction. London (UK): National Institute for Clinical Excellence (NICE); 2003 Nov. 25 p. (Technology appraisal; no. 73).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Nov

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction. Quick reference guide. London (UK):

National Institute for Health and Clinical Excellence (NICE); 2003 Nov. 3 p. (Technology appraisal 73). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

- Systematic review of the effectiveness and cost-effectiveness, and economic evaluation, of myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction. Assessment report. 2003 May. 158 p. Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N0372. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria can be found in Appendix C of the original guideline document.

PATIENT RESOURCES

The following is available:

- Myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction. Understanding NICE guidance - information for people with angina and myocardial infarction (coronary artery disease), their families and carers, and the public. London (UK): National Institute for Health and Clinical Excellence (NICE); 2003 Nov. 10 p. (Technology appraisal 73).

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the Department of Health Publications Order Line 0870 1555 455. ref: N0373. 11 Strand, London, WC2N 5HR.

NGC STATUS

This NGC summary was completed by ECRI on March 8, 2006.

has not been involved in the development or adaptation of NICE guidance for use in any other country. The full versions of all NICE guidance can be found at www.nice.org.uk.

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